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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,832	03/22/2001	Richard L. Mueller	5756-0012.30	6135

7590 06/23/2003

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EXAMINER	
SHAY, DAVID M	

ART UNIT	PAPER NUMBER
3739	12

DATE MAILED: 06/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.	Applicant(s)
09/816832	Mueller
Examiner	**Group Art Unit**
[illegible]	3739

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE —3— MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on March 20, 2003.

☑ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1 - 9 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1 - 9 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Int rview Summary, PTO-413

☐ Notice of R ferences Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Revi w, PTO-948

☐ Other _____

Office Action Summary

The rejection set forth in the previous office action are hereby repeated.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 6, 8, and 9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Narciso, Jr. or Chen et al.

In Narciso, Jr., see Figure 4, sleeve 44 is transparent and non-inflatable, the device includes a guidewire lumen (element 16) for a guidewire (not shown – see column 3, lines 44-45), both the guidewire lumen and perfusion channel (element 51, figure 5) can also accommodate a light transmissive fluids; and a proximal end connector for the fiber optic bundle (see figure 1, elements 17 and 18 and column 3, lines 28-34).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spears in combination with Chen et al. Spears teaches a method such as claimed except the guidewire removal, the optic fiber insertion and the time period. Chen et al teaches a PDT method wherein the optical fibers are inserted after the guidewire is removed. It would have been obvious to the artisan of ordinary skill to employ the guidewire removal and fiber insertion steps of Chen et al in the method of Spears, since this would provide easier catheter placement or alternatively to employ the method of Chen et al to treat plaque, since Chen et al does not require the treatment of any particular tissue and in either case to treat a diseased portion with a lesser thickness so as to require only 10-20 minutes of exposure, thus producing a method such as claimed.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al or Narciso, Jr. Chen et al and Narciso, Jr. each teach a device such as claimed (see figures 12A-D and 5, respectively), except for the lumen diameter. It would have been obvious to the artisan of

ordinary skill to employ a lumen in the claimed range, since this is an appropriate size to accommodate a guidewire and solves no particular problem in the art, thus producing a device such as claimed.

Regarding the rejection under 35 USC 102, applicant argues that Narciso, Jr. does not include a non-inflatable translucent distal end sleeve. As set forth in the explanation of the rejection based on Narciso, Jr. element 44 fulfills this recitation in the claim. Applicants "comprising" – type claim language does not preclude the presence of additional, inflatable structures (e.g. balloon 23).

With respect to the Chen et al reference applicant argues that claim 6 "recites a proximal end catheter port through which a light transmissive fluid can be injected through the catheter into the lumen of the distal end sleeve, and that a light beam transmitted through the bundle is scattered by the fluid..." and asserts that these elements are not disclosed in Chen et al. The examiner must respectfully disagree. Figures 12 A-12D of Chen et al show an optical fiber embodiment of the device (see column 19, lines 27-32) with a guide wire (see column 19, lines 36-37) as can be readily seen from figure 12B, the lumens containing the fibers are over sized leaving a space therein that can accommodate a light transmitting fluid, and at the time the fiber optics are threaded into the passages, will have a port allowing the injection of such a fluid. As to the functional phrase contained in the whereby clause, the examiner notes, firstly that this phrase is not in the proper form to be treated under 35 USC 112, sixth paragraph (see MPEP 2181) and thus is not accorded great weight. However even assuming the functional phrase did conform to the language to invoke 112, sixth paragraph, as the photons which make up all light are subject to the laws of quantum mechanics, some of the photons must be scattered by the

transparent fluid, since the only medium that light can propagate through while remaining totally unscattered is vacuum. Thus Chen et al clearly contains the structures recited in the claims to which is applied.

Regarding the rejections under 35 USC 103, applicant argues that the lumen of the glass fiber of Spears is not in fluid communication with the catheter lumen. The examiner must respectfully disagree, as the guidewire can pass from the catheter lumen to the fiber lumen (see column 4, lines 58-63). Thus, since Chen et al clearly teach the injection of the light active fluid into the lumen of the catheter after removal of the guidewire (see column 19, lines 36-44 and column 20, lines 31-36), the combined teachings of Spears and Chen et al do teach the claimed method even though it is not wholly taught by one reference or the other separately.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the proximal end catheter port must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Applicant's arguments filed March 20, 2003 have been fully considered but they are not persuasive. The arguments are not convincing for the reasons set forth above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number 308-2215.

. Shay/Dl

June 3, 2003

DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330